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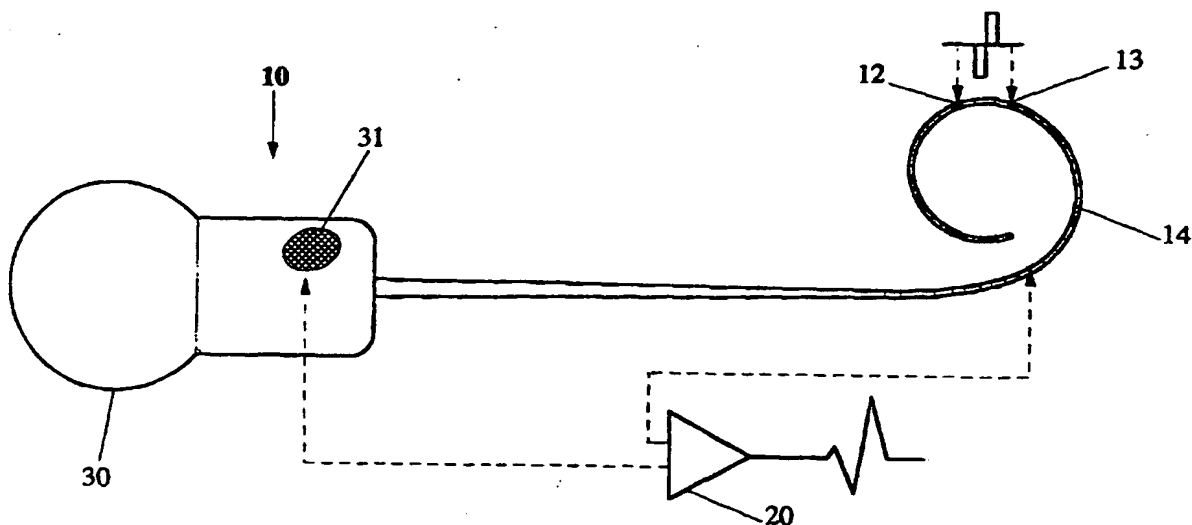
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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| <p>(21) International Application Number: PCT/AU93/00670 (22) International Filing Date: 22 December 1993 (22.12.93) (30) Priority Data: PL 6522 22 December 1992 (22.12.92) AU (71) Applicant (for all designated States except US): COCHLEAR PTY. LTD. [AU/AU]; 14 Mars Road, Lane Cove, NSW 2066 (AU). (72) Inventors; and (75) Inventors/Applicants (for US only): NYGARD, Tony, Mikeal [FI/AU]; 14 Stacey Close, Karing, NSW 2250 (AU). DALY, Chris, Newton [AU/AU]; 95 Beryl Crescent, Bilgola Plateau, NSW 2107 (AU). PATRICK, Jim, Finlay [AU/AU]; 5 Arding Street, Lane Cove, NSW 2066 (AU). MONEY, David, Kerry [AU/AU]; 50 Blackbutt Avenue, Pennant Hills, NSW 2120 (AU). (74) Agent: WATERMARK PATENT & TRADEMARK ATTORNEYS; Level 4, Amory Gardens, 2 Cavill Avenue, Ashfield, NSW 2131 (AU).</p> | | <p>(81) Designated States: AU, CA, JP, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published With international search report.</p> |

(54) Title: TELEMETRY SYSTEM AND APPARATUS



Note: INTERNAL TO IMPLANT

(57) Abstract

A system is disclosed for enabling telemetry from an audio prosthesis, preferably a cochlear prosthesis. An electrode array (10) is used for both delivering stimuli and for seeking evoked potentials. Preferably a delay is provided between stimulus and measurement. The sensing electrodes (14, 31) are distinct from the stimulus electrodes (12, 13).

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TELEMETRY SYSTEM AND APPARATUS

Field of Invention

This invention relates to a telemetry system and apparatus for recovering data from an auditory prosthesis.

5 Background Art

After an auditory prosthesis, such as a cochlear prosthesis, is surgically implanted, it is advantageous if data can be obtained about the actual performance of the electrode array, and the response of the auditory nerve to stimulation. This enables detection or confirmation of normal operation of the
10 device, and optimisation of stimulus parameters in an objective fashion. Similar requirements apply to other implanted auditory prostheses.

It is an object of the present invention to provide a telemetry system for an auditory prosthesis such that the required data may be effectively, and with minimal inconvenience to a patient, monitored externally.

15 Summary of Invention

According to one aspect the present invention comprises a system for measuring the response of a neural system to stimulation by an auditory prosthesis, wherein selected stimulus electrodes provide an electrical stimulus, and after a predetermined period a potential is detected across a selected
20 sense pair of electrodes, said potential being indicative of at least one parameter of response by said neural system.

Preferably after said electrical stimulus, all electrodes are open circuited for a predetermined period prior to said potential being detected. Preferably the system includes an amplifier and means for nulling said amplifier. Preferably
25 said means for nulling nulls said amplifier during said predetermined period. Preferably said means for nulling comprises a plurality of cascaded gain stages, adapted at the end of said period to release said stages sequentially such that any offset voltage is substantially cancelled.

Preferably the stimulus electrodes are different to the sensing electrodes.

30 Preferably the auditory prosthesis is a cochlear prosthesis. Preferably the response measured is the evoked action potential of the auditory nerve.

Preferably said cochlear prosthesis includes an array of electrodes

including both intra-cochlear and extra-cochlear electrodes.

According to a further aspect the invention comprises a telemetry system for measuring the response of a neural system to stimulus by an auditory prosthesis, wherein said auditory prosthesis includes a electrode array, said
5 array being used for stimulation and to sense said response.

Preferably said measurement occurs a predetermined time after stimulation has occurred.

Preferably after electrical stimulation, all electrodes are open circuited for a predetermined period prior to said response being detected.

10 Preferably the auditory prosthesis is a cochlear prosthesis. Preferably the response measured is the evoked action potential of the auditory nerve.

Preferably said cochlear prosthesis includes an array of electrodes including both intra-cochlear and extra-cochlear electrodes.

Preferably the stimulus electrodes are different to the sensing electrodes.

15 According to another aspect the present invention comprises an implantable auditory prosthesis, comprising an intra-cochlear electrode array, and at least one extra-cochlear electrode.

According to the present invention, it has been discovered that a most effective way of measuring response to neural stimulation, particularly for
20 measuring evoked auditory potential but also applicable to other stimulation regimes, is to use the stimulus array itself to receive the response. To enable this to operate effectively, the electrodes of the stimulus array are preferably open circuited for a period, after which the induced response may be measured. This removes any requirement for additional separate measurement sensors to be
25 implanted. In a multi-electrode array such as is generally utilised in a cochlear implant, different electrode pairs are preferably used for stimulus and measurement.

Brief Description of Drawings

The invention will now be described in more detail with reference to the
30 drawings, in which:

Figure 1 illustrates the general arrangement of the inventive system;

Figure 2 is an overview in block form of the inventive system;

Figure 3 is a timing diagram showing the stimulus and measurement sequence; and

Figure 4 is a schematic diagram showing one circuit arrangement for the preferred amplifier arrangement according to the present invention.

5 Detailed Description

Referring to Figure 1, it is initially noted that the electrode array 10 is used both for stimulating, and for detecting the evoked response. Detected data is transmitted via the RF link already provided for transmitting power and data to the implant 10.

10 It will be noted that the implant, in addition to the intra-cochlear electrodes, preferably includes one or more extra-cochlear electrodes 31. For the telemetry of evoked neural potentials, it is greatly preferred to use different electrodes for delivering the stimulus, and for sensing the evoked action potential of the auditory nerve (EAP). Thus, for monopolar stimulation and
15 measurement, one extra-cochlear electrode may be used for stimulating, and the other for sensing.

The EAP may according to the present invention be measured across any two sense electrodes. The waveform on the sense electrodes consists of the EAP nerve response plus the stimulus artefact. The stimulus artefact is decaying
20 exponentially, but can in many cases be orders of magnitude larger than the nerve response itself. The electrode pair chosen will optimally detect maximum EAP gradient, and minimum stimulus artefact. The illustrative sense pair with reference to figure 1 uses intra-cochlear electrode 14 and extra-cochlear electrode 31.

25 Similarly, the stimulus pair 12, 13 may be any selected electrode pair. The optimal sense pair may vary with the stimulus pair selected, and may vary from patient to patient, as would be understood by those skilled in the art. Whilst it is preferred that the sense electrode pair be distinct from the stimulating electrode pair, the present invention encompasses the use of the same
30 electrodes or electrode pair.

The sense pair potential difference is amplified by a suitable amplifier 20 to produce (ultimately) an EAP measurement on apparatus external to the

patient. The amplified signal is sampled at 16 intervals and transmitted via the RF link, each sample being a pair of pulses with a pulse separation proportional to the amplifier output.

Figure 2 illustrates in block form the internal and external aspects of the system.

Considering firstly the external system, the overall arrangement is controlled via digital processor 45, which may be a personal computer or similar device with suitable interfaces. Processor 45 drives the transmitter controller 46 and thus the transmitter stage 43 to send signals via RF link 41 to the implant 10. Transmitted telemetry data is received via RF link 41 passed through receiver 42 and comparator and timer/controller stage 44.

Commands are received in the implant 10 via RF link by receiver coil 30 and pass via receiver stage 32 to decoder/controller 34, which sends suitable commands to the EAP amplifier/telemetry controller 35 and to switch controller 36. Switch controller 36 controls the stimulation of selected pairs of electrodes. The sense electrode signal is amplified by EAP amplifier 40 and the telemetry controller processes the amplified signal for transmission via transmitter stage 33 and RF link 30 to the external system 40.

It will be appreciated that any suitable arrangement may be substituted for the precise arrangement outlined above. The overall technique for RF communication for powering and communicating with implanted devices is well known from, for example, commercially available devices manufactured by Cochlear Pty Ltd. However, the present invention should not be considered as limited to this mode of communication - the invention is independent of the communications mode, and could if desired be implemented in a directly connected system, for example. Preferably, the implanted system is integrated into a single chip as far as possible. Similarly, it will be apparent that with suitable modifications the present invention is applicable to other stimulation regimes and sites. The EAP application is used for the purposes of illustration.

The operation of EAP detection according to the present invention can best be understood with reference to the timing diagram of Figure 3. The top line illustrates stimulus via the stimulus electrode pair : the bottom represents

time. In the preferred embodiment the all electrodes are short circuit prior to time t_2 or stimulation.

At time t_2 , a stimulus pulse (illustratively a square biphasic pulse) is applied to stimulus pair 12, 13. Stimulus is completed at t_1 and all electrodes 5 (including the stimulus electrodes) are left open circuit. The amplifier 35 is nulled until time t_0 . At time t_0 (for example), sampled measurements are taken at times $t_1, t_2 \dots$ until time t_{16} . After t_{16} , the electrodes are again short circuited, ready for a further cycle of stimulus and EAP measurement. Note that short circuit before and after stimulus is one way of ensuring charge balance, but it is 10 not necessary for recording the nerve response.

Preferably, the time between t_2 and t_0 is about or slightly shorter than 400 μs , as this is a typical time between stimulus onset and nerve response occurrence. Of course, this may be varied as is appropriate for a given application. The period between t_1 and t_0 is preferably programmable such that 15 the nulling period ends just before the expected EAP occurrence, thereby minimising the detection of stimulus artefacts. This programmable delay is controlled by the telemetry controller 35.

Open circuiting all electrodes (including the stimulus electrodes after stimulation) further reduces the stimulus artefact and the required dynamic 20 range of the amplifier. This arrangement has a further advantage in that one of the sense electrodes can be connected to the common supply rail and a single ended amplifier can be used. If preferred, a fully differential input stage could be used instead of the single ended amplifier.

The sample intervals are typically 100 μs , hence the sampling window is 25 1.5 to 2.0 ms. Both programmable delay time and the sampling period can be adjusted over a wide range to optimise the position and duration of the measurement window. This also allows recording of nerve responses other than the auditory response which result from the stimulus.

The measurement sequence is preferably repeated several times and 30 averaged to further increase the signal to noise ratio of the measurement. The recorded signal required further post processing to eliminate the stimulus artefact from the composite signal. This could involve techniques known in this

art such as masking stimulus and alternate phase sequences.

Figure 4 illustrates a preferred implementation of the amplifier using four cascaded single-ended gain stages AMP₀, AMP₁, AMP₂, AMP₃. Illustratively, each stage has a gain of 20dB. Any suitable amplifier design may be used for 5 individual gain stages, as would be well understood by those skilled in the art. All amplifiers are preferably nulled before the recording period (initial delay) and any offset voltage is stored on the input capacitors. The length of the nulling period is programmable and controlled by telemetry controller 35.

At the end of the nulling period (Figure 3,t₀) the amplifier stages are 10 released sequentially, so as to compensate for offset voltage due to the charge injection into the previous stage.

It can be seen from Figure 4 that AMP₀ and AMP₁ have a self-biased DC offset, while AMP₂ and AMP₃ are biased around V_{ref} which is approximately half way between the supply rails, so that the output range is optimised. The last 2 15 stages have switchable gain of 20dB or 0dB, and as a result the amplifier may be set for gain of 40,60 or 80dB.

This arrangement allows for accurate measurement of V_{EAP} , without the necessity to separately compensate or adjust for offsets.

It will be appreciated that variations and additions are possible within the 20 spirit and scope of the invention.

CLAIMS

1. A system for measuring the response of a neural system to stimulation by an auditory prosthesis, wherein selected stimulus electrodes provide an electrical stimulus, and after a predetermined period a potential is detected across a selected sense pair of electrodes, said potential being indicative of at least one parameter of response by said neural system.
2. A system according to claim 1, wherein after said electrical stimulus, all electrodes are open circuited for a predetermined period prior to said potential being detected.
3. A system according to claim 1 or claim 2, wherein the auditory prosthesis is a cochlear prosthesis.
4. A system according to claim 3, wherein said response measured is the evoked action potential of the auditory nerve.
5. A system according to any one of the preceding claims, wherein the stimulus electrodes are different to the sensing electrodes.
6. A system according to claim 3, wherein said cochlear prosthesis includes an array of electrodes including both intra-cochlear and extra-cochlear electrodes.
7. A system according to claim 2 including an amplifier and means for nulling said amplifier.
8. A system according to claim 7 wherein said means for nulling nulls said amplifier during said period.
9. A system according to claim 7 or claim 8 wherein said means for nulling comprises a plurality of cascaded gain stages, adapted at the end of said period

to release said stages sequentially such that any offset voltage is substantially cancelled.

10. A telemetry system for measuring the response of a neural system to stimulus by an auditory prosthesis, wherein said auditory prosthesis includes a electrode array, said array being used for stimulation and to sense said response.

11. A system according to claim 10, wherein said sensing occurs a predetermined time after stimulation has occurred.

12. A system according to claim 10, wherein after electrical stimulation, all electrodes are open circuited for a predetermined period prior to said response being sensed.

13. A system according to claim 12 including an amplifier and means for nulling said amplifier.

14. A system according to claim 13 wherein said means for nulling nulls said amplifier during said period.

15. A system according to claim 13 or claim 14 wherein said means for nulling comprises a plurality of cascaded gain stages, adapted at the end of said period to release said stages sequentially such that any offset voltage is substantially cancelled.

16. A system according to any one of claims 10 to 15, wherein the auditory prosthesis is a cochlear prosthesis.

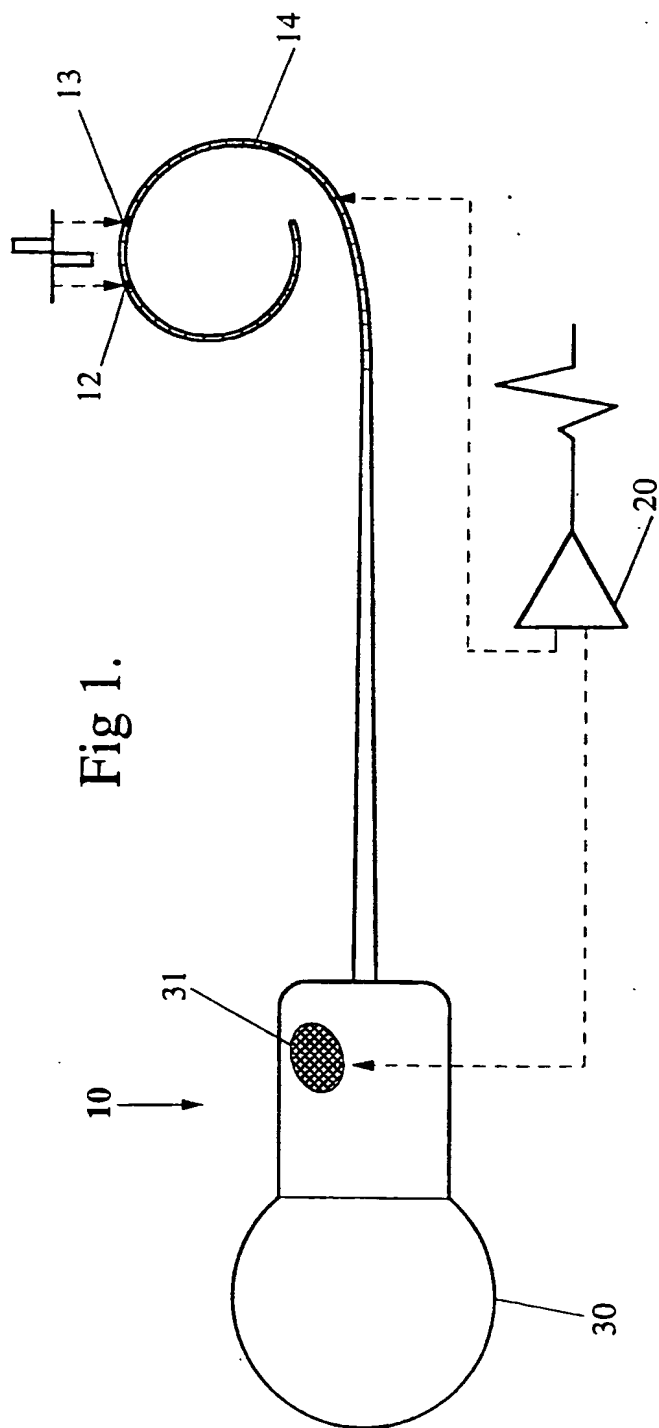
17. A system according to claim 16, wherein said response measured is the evoked action potential.

18. A system according to claim 10, wherein said cochlear prosthesis includes an array of electrodes including both intra-cochlear and extra-cochlear electrodes.

19. A system according to any one claims 10 to 18, wherein the stimulus electrodes are different to the sensing electrodes.

20. An auditory prosthesis including a system according to any one of the preceding claims.

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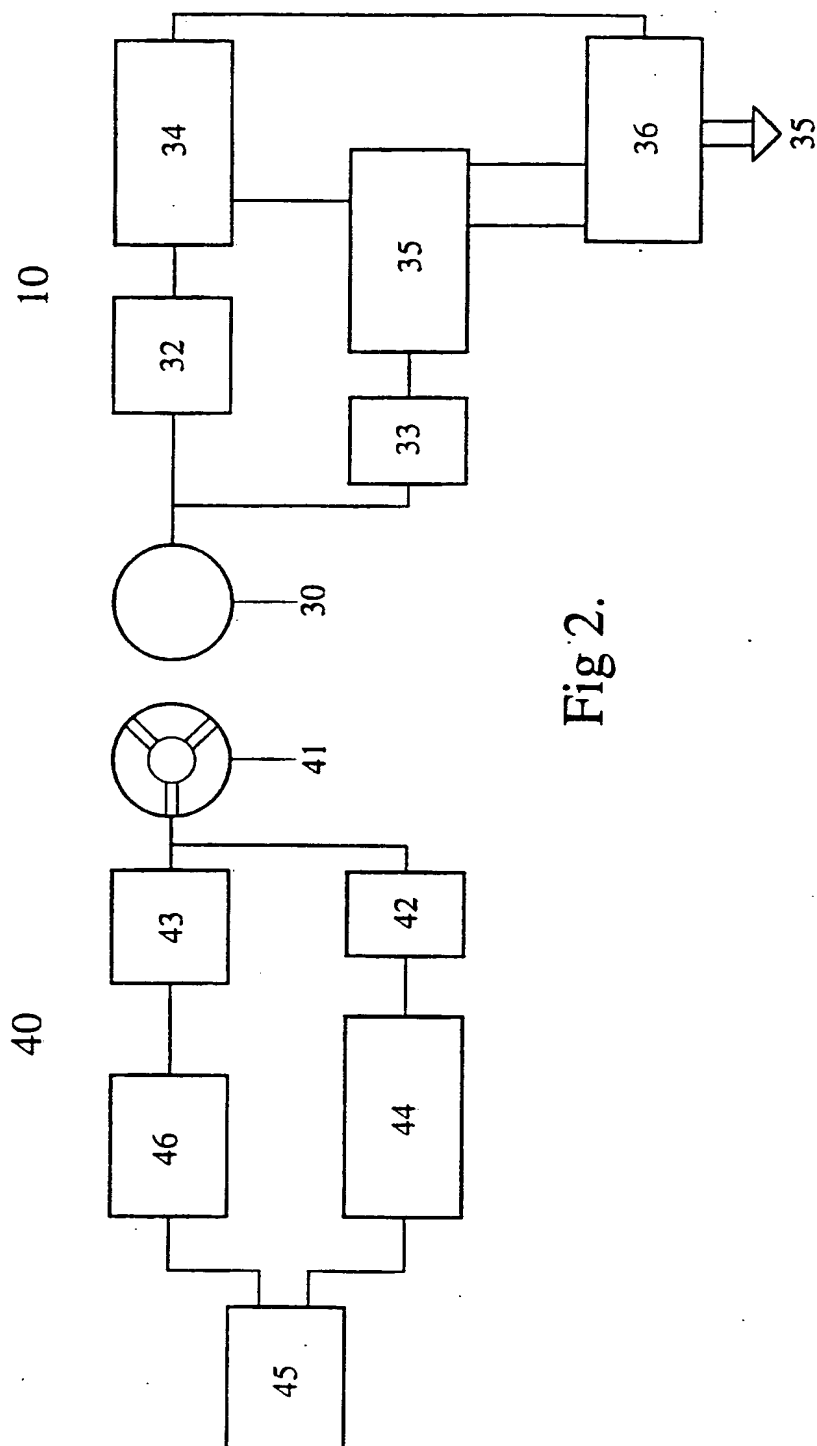
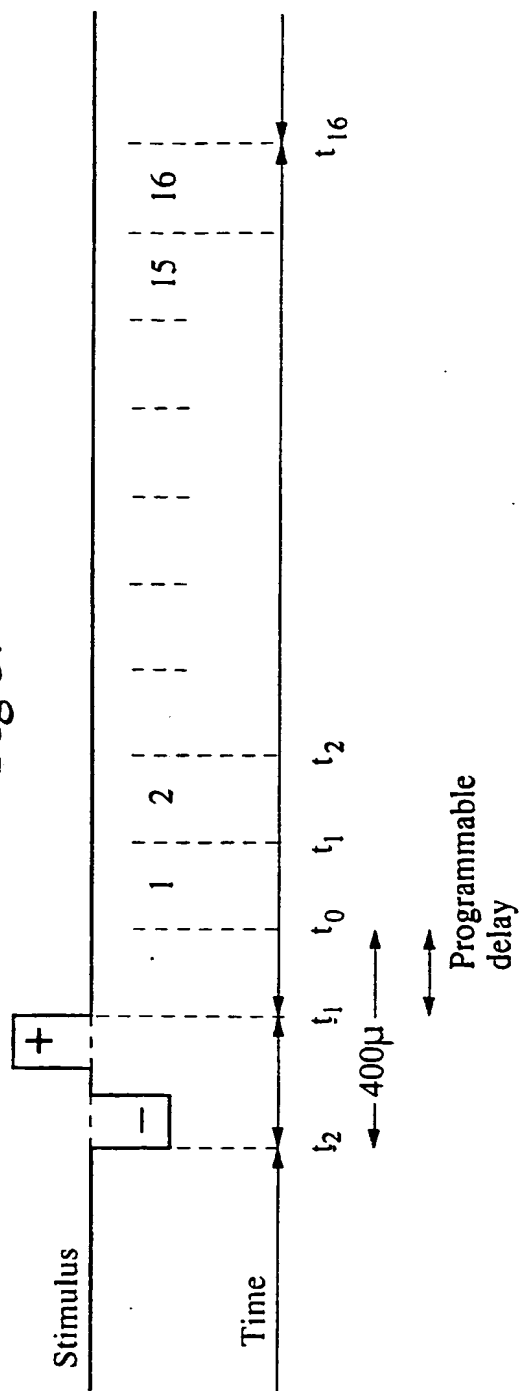


Fig. 2.

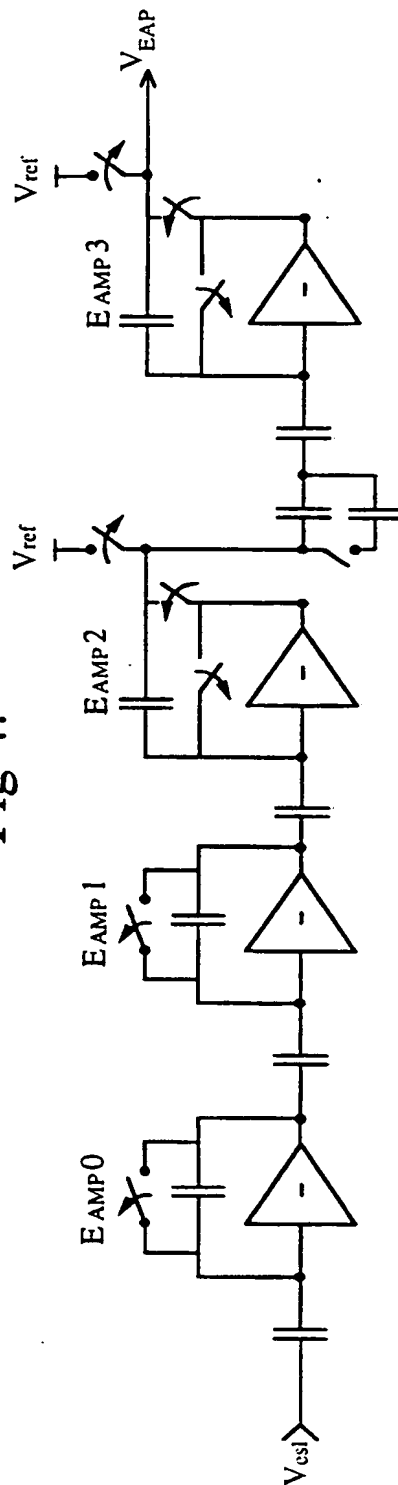
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Fig 3.



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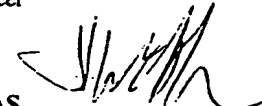
Fig. 4.



INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU 93/00670

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| A. CLASSIFICATION OF SUBJECT MATTER Int. Cl. ⁵ A61B 5/12 A61F 11/00 According to International Patent Classification (IPC) or to both national classification and IPC | | | | | |
| B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC : A61B 5/12 A61F 11/00 11/04 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched AU : IPC as above Electronic data base consulted during the international search (name of data base, and where practicable, search terms used) DERWENT: (1) electrocochleo: (2) (A61B 5/05) and (ear: or cochlear: or auditory) JAPIO | | | | | |
| C. DOCUMENTS CONSIDERED TO BE RELEVANT | | | | | |
| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to Claim No. | | | |
| X Y | US,A, 4535785 (VAN DEN HONERT et al) 20 August 1985 (20.08.85) column 8 line 1 - column 9 line 11, abstract, figures 3A, 3B | 1, 3, 5 10 | | | |
| Y | GB,A, 2124495 (TELETRONICS PTY LTD) 22 February 1984 (22.02.84) abstract, page 1 line 1 - page 2 line 120, page 4 line 11 - page 5 line 37 figure 3 | 10 | | | |
| A | EP,A, 214527 (MINNESOTA MINING AND MANUFACTURING COMPANY) 18 March 1987 (18.03.87) See entire document | 1-9 | | | |
| <div style="display: flex; justify-content: space-between;"> <div> <input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. </div> <div> <input checked="" type="checkbox"/> See patent family annex. </div> </div> | | | | | |
| <table style="width: 100%; border: none;"> <tr> <td style="width: 33%; vertical-align: top;"> * Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed </td> <td style="width: 33%; vertical-align: top;"> "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family </td> <td style="width: 33%;"></td> </tr> </table> | | | * Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family | |
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| Date of the actual completion of the international search 8 March 1994 (08.03.94) | | Date of mailing of the international search report 16 March 1994 (16.03.94) | | | |
| Name and mailing address of the ISA/AU AUSTRALIAN INDUSTRIAL PROPERTY ORGANISATION PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No. 06 2853929 | | Authorized officer <div style="text-align: center;"> for  SUE THOMAS </div> Telephone No. (06) 2832454 | | | |

INTERNATIONAL SEARCH REPORT

International application No.
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| C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT | | |
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| Category* | Citation of document, with indication, where appropriate of the relevant passages | Relevant to Claim No. |
| A | EP,A, 247649 (THE COMMONWEALTH OF AUSTRALIA) 2 December 1987 (02.12.87) See entire document | 1-20 |
| A | EP,A, 241101 (THE COMMONWEALTH OF AUSTRALIA) 14 October 1987 (14.10.87) See entire document | 1-20 |
| A | EP,A, 124930 (THE COMMONWEALTH OF AUSTRALIA) 14 November 1984 (14.11.84) See entire document | 1-20 |

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/au 93/00670

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Document Cited in Search Report | | Patent Family Member | | | |
|--|---------|----------------------|----------|----|----------|
| US | 4535785 | US | 4535785 | | |
| GB | 2124495 | AU | 13595/83 | AU | 71088/87 |
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| | | EP | 214527 | JP | 62044250 |
| | | US | 4706682 | JP | 63013983 |
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